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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,597	01/25/2002	Christian Eickmeier	1/1186	2930

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EXAMINER

BERNHARDT, EMILY B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 12/17/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
10/057,597

Applicant(s)  
EICKMEIER et al.

Examiner  
Emily Bernhardt

Art Unit  
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some\* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_                      6) ☐ Other:

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Claims 2-4,6-8,and 9-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1.Claims 2-4,6-8, 10-12, 14-16 reciting/embracing hydrates are outside the scope of main compound claim 1 from which they all ultimately depend. Insertion of “or hydrates thereof” into main claim 1 would overcome this rejection.

2.Scope of method claims 9-16 are of indeterminate scope. Defining a disease(s) by its (their) underlying cause renders the scope of intended uses indeterminate since the claim language may read on diseases not yet known to be caused by or affected by such action or in ways not yet understood. Additionally, determining whether a given disease responds or not to sodium-hydrogen exchange inhibition involves much experimentation since a negative response from one patient does not mean the drug isnt useful as no drug has 100% effectiveness. Thus what “success rate” determines if a particular inhibitor is effective and how many patients (and dosage regimens) need to be tested? The test for determining compliance with 35 USC 112, par.two is whether applicants have clearly defined “their” invention not what may be discovered by future research as this type of claim language clearly requires.

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Claims 9-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Scope of disorders covered by instant method claims appears to cover at least those described on p.5 which include whole class of disorders as well as any and all tumor types. The notion that sodium-hydrogen exchange inhibition, the activity relied on herein, is known for such a range of uses is not substantiated by the art provided by the examiner which deals with known drugs having this activity useful for treating myocardial ischaemia and reperfusion injury as well as hypertension. See the medline abstracts provided.

Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied on are reasonably predictive of in vivo efficacy by those skilled in the art. See for example, In re Ruskin 148 USPQ 221; Ex parte Jovanovics 211 USPQ 907. Any evidence relied on by applicants must clearly show a reasonable expectation of in vivo success for any additional diseases that may still be embraced in response to this action. Also note MPEP. 2164.05(a).

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,5,9,13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eickmeier (US'207 or WO'176) and Buerger (US'335 or WO'253). Each of the commonly assigned references independently render instant subject matter obvious as they are both drawn to the same basic compounds for the same uses. See col.1 and working examples in Eickmeier and the same as well as claims in Buerger. In particular, in Eickmeier see <sup>2</sup> eg.4 and in Buerger see eg.7. The former differs only in nature of salt form and the latter while a HCl salt as herein has methanesulfonyl in place of trifluoromethyl. Note that both references teaches the interchangeability of various salts as well as trifluoromethyl in place of methanesulfonyl on benzene ring in Buerger. Thus it would have been obvious to one skilled in the art at the time the invention was made to replace the salt of eg.4 with HCl and methanesulfonyl of eg.7 with CF<sub>3</sub> and in so doing obtain instant compound for treating one or more uses taught by the applied art.

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While evidence of common ownership may now be enough to disqualify commonly assigned art under 103 based on 102(e) as well as 102(f) or (g) in view of the passage of the American Inventors Protection Act, there must be provided a clear statement by applicants, attorney or agent of record that instant application and US'207 and '335 **at the time the instant invention was made** were commonly owned. See 1241 OG 96, December 26,2000. However, WO patent equivalents would not be disqualified under this new law. To overcome the rejection with a showing note both prior art compounds mentioned above must be tested against instant HCl salt and any showing be in verified form Note *In re Johnson* 223 USPQ 1260.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ

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761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,5,9 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,323,207. Although the conflicting claims are not identical, they are not patentably distinct from each other because they embrace overlapping subject matter. Instant HCl salt form is generically covered by the claim language.

US'335 is limited to methanesulfonyl derivatives.

**Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.**

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A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

  
**EMILY BERNHARDT**

**PRIMARY EXAMINER**

**GROUP 1600**